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10/676,280	09/30/2003	Timothy R. Billiar	14022-011001	7071

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
04/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/676,280	BILLIAR ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,21-40 and 55-65* is/are pending in the application.

4a) Of the above claim(s) *4-9 and 21-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 10, 11 and 55-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS, declaration under 37 CFR 1.132, amendment and remarks, all filed 1/12/2009. Claims 15-20 are canceled. Claim 55 is amended. Claims 1-11, 21-40 and 55-65 are pending. Claims 4-9 and 21-40 are withdrawn form consideration.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3, 10, 11 and 57-65 remain rejected under 35 U.S.C. 112, first paragraph for reasons of record and reiterated herein below, because the specification, while being enabling for certain specific concentration of CO effective to treat hemorrhagic shock, does not reasonably provide enablement for all concentration CO effective to treat hemorrhagic shock. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is scope of enablement.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue

experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient number of the factors are discussed below for a *prima facie* case.

1) Nature of the invention

The nature of the invention is the administration of carbon monoxide to a patient in order to treat hemorrhagic shock.

2) State of the prior art

Carbon monoxide (CO) is known in the art to be toxic to humans causing exhaustion and headache at levels of as low as 70 ppm (Omaye, "Metabolic modulation of carbon monoxide toxicity," in Toxicology 180 (2002) 139-150). The instant specification at paragraph [0040] talks about using Co at levels of 10 ppm to 3000 ppm for the treatment of hemorrhagic shock.

3) The predictability or lack thereof in the art

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18

(CCPA 1970) indicates that the more unpredictable an area is, the more specific guidance is required to enable the artisan to practice the full scope of the claimed invention.

In the instant case, the scope of the claimed invention spans all concentrations of CO for effectively treating hemorrhagic shock. Also while the instant disclosure at paragraph [0040] envisions the use of 10-3000 ppm CO for inhalation, the prior art describes CO to be toxic at levels of as low as 70 ppm.

4) Amount of direction and guidance present

The direction and guidance provided is limited to amounts described in paragraph [0040] and not to all possible amounts. The listing of the amounts of CO at paragraph [0040] is an invitation to experiment because (see 5 below).

5) The presence or absence of working Examples

The working examples fail to provide any amount of CO useable in the invention, and by implication then refers back to the amounts disclosed in paragraph [0040]. The working examples do not correlate with the scope of the claims.

6) Quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine what concentration of CO to use that would not provide toxicity since applicants envision concentrations of 10-3000 ppm and Omaye discloses that CO levels of 70 ppm is toxic ands the claims is open ended to any amount of CO.

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to

engage in undue experimentation to test and use the scope of the claimed invention encompassed in instant claims, with no assurance of success.

This rejection can be overcome by the concentrations of CO effective for claimed method.

Response to Arguments

3. Applicant's arguments filed 1/12/09 have been fully considered but they are not persuasive.

A) Applicant argues that the 70 ppm or higher CO could be administered could be administered to individuals because Omaye states that the effect of chronic exposure to 70 ppm CO is exhaustion in healthy patients and more in angina patients and headaches and that Doctors administering CO to patients experiencing hemorrhagic shock would clearly be able to weigh any effects such as exhaustion or headaches or "potentially greater adverse effects" against the therapeutic value of CO in the treatment of hemorrhagic shock that may lead to multiple organ failure. The examiner disagrees with the applicant. i) the claims at issue directs the practitioner to use any and all amounts, and the implication of applicant's statement that the artisan "Doctor" has the skills to weigh the benefits of CO administration in any amounts, even in the face of "potentially greater adverse effects" against the "therapeutic value of CO" is that applicant is requiring the practitioner to investigate levels of CO that may be suitable and to embark on as it were on a trial and error expedition. ii) while CO exposure has been extensively studied as per applicant, the prior cited by applicant does not teach that all and any levels of CO should be used to treat hemorrhagic shock. iii) applicant's arguments that at ambient concentration of 100 ppm CO level, individuals do not reach 10% COHb level until after more than five hours of continuous exposure, and that one can administer a large concentration of CO

for a short time period and achieve the same level of Co exposure, with reference to Stewart. The examiner disagrees. For example, ambient CO levels have a specific ambient pressure and temperature and the claims have not specified what those operational conditions for the CO administration would be. For feeding a patient with CO does not represent ambient conditions. The pressure at which the CO is administered is not stated, the expected HB levels of the CO is not stated in the claims and the rate at which the CO is administered is not stated and cannot be compared to passive intake of CO from ambient conditions. Furthermore, Stewart is clear as per applicant, that patient is exposed to 50 ppm CO for 3 hours for a COHB level of 5%. The claims do not have any stipulations as to the time of exposure and as to the levels of exposure and the conditions of exposure in terms of pressure and temperature and rate of infusion of the CO. Therefore, the scope of the enabling disclosure relative to the scope of the claims and when the full scope of what is claimed is analyzed based on what is enabled, the question is as follows as stated in the MPEP at 2164.08 [R-2] as follows in relevant sections: "The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims." "The specification must teach those skilled in the art how to make and use the **full scope of the claimed invention without undue experimentation**."

The claims are seeking protection for all and every level of CO to be administered to a subject having hemorrhagic shock. The specification envisions specific concentrations for treating hemorrhagic shock. The protection sought by the claim is broader than what is enabled

by the disclosure. The Omaye reference is a negative teaching and raises the issue of what levels of CO is enabled

B) Applicant argues that the working examples shows levels of CO administered, but the working examples do not represent all the levels that are covered by the scope of the claims. The scope of enablement provided to one skilled in the art by the disclosure is not commensurate with the scope of protection sought by the claims. The protection sought by the claim is broader than what is enabled by the disclosure.

C) Applicant argues that the quantity of experimentation is not undue because the relative skill of the artisan is high and as such no further guidance is necessary. While the examiner agrees with applicant that that the quantity of experimentation needed is one of the factors, it is noted that applicant's arguments that there is no undue experimentation is not persuasive, because by applicant's own admission, the skilled artisan has the capability of weighing the benefits of uncontrolled amounts of CO infusion against multiple organ failure from that may result from hemorrhagic shock. In the present case, the artisan must determine the rate of the CO infusion, the level of exposure of the CO, the time of exposure of what ever level of CO and pressure of the CO infusion. This is undue experimentation in this instance that no CO exposure level, time of exposure and rate of the infusion and the pressure under which the infusion is carried out is designated.

The finding of lack of commensurate **scope of enablement** is maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 10 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipate by Fujita et al. ("Paradoxical rescue from ischemic lung injury by inhaled carbon monoxide driven by depression fibrinolysis," Nature Medicine, 7, 598-604, 2001) for reasons of record and reiterated herein below.

Fujita discloses that inhaled CO protects against ischemic lung tissue injury (see the whole document). Inhalation meets claim 3 and lung tissue injury meets claim 1. Since ischemia is not limited to one organ and can be more generalized as in e.g. hemorrhagic shock as evidence by Bar-Or et al. (US 2005/0215468) in paragraph [0004] where it describes ischemia occurs in hemorrhagic shock in a more generalized sense. Thus Fujita meets claims 1-3, 10 and 11 because treating ischemia that occurs in hemorrhagic shock inherently treats the condition of hemorrhagic shock.

6. Claims 1-3, 10 and 11 remain rejected under 35 U.S.C. 102(e) as being anticipated by Pinsky et al. (US 2005/0048133 A1) for reasons of record and reiterated herein below.

Pinsky treats tissues damaged (paragraph [0099], [0164]) by ischemic disorders (paragraph [0017]) with carbon monoxide inhalation (paragraphs [0028]-[0030], [0049], [0055], [0061], [0062]). Ischemia is shown by the prior art to be generalized conditions deriving from hemorrhagic shock as evidenced by Bar-Or et al. (US 2005/0215468) in paragraph [0004] where it describes ischemia occurs in hemorrhagic shock in a more generalized sense. Thus Pinsky meets claims 1-3, 10 and 11 because treating ischemia that occurs in hemorrhagic shock inherently treats the condition of hemorrhagic shock.

Response to Arguments

7. Applicant's arguments filed 1/12/09 have been fully considered but they are not persuasive. Applicant argues that:

D) Treatment of hemorrhagic shock is not inherent in Fujita because the specification at paragraph [0037] and Websters Medical Dictionary defines shock as other than ischemia, Martel's definition of hemorrhagic shock is not ischemia. The examiner disagrees. Applicant had previously stated on the record that, although ischemia can occur in hemorrhagic shock, that the office cannot use that as a general license to construe the terms "ischemia" and hemorrhagic shock as one and the same the terms. It is also well known that ischemic conditions occurs in hemorrhagic shock as evidenced at paragraph [0004] of Barshalom, IngentaConnect Detection of organ ischemia during hemorrhagic shock, and Pelc et al., in Radiology, 1998, pp 219-225. The Office relies on prior art teachings as evidence and that is why applicant's argument is not persuasive that ischemia of the lung is localized and Fujita and Pinsky do not rule out other organs from being affected by what is happening in the lungs. It is further noted that the

invention treats hemorrhagic shock by *administering CO via inhalation* (instant claim 3). Fujita administers CO via inhalation also and thus inherently treats hemorrhagic shock when ischemia, which occurs in hemorrhagic shock is treated. The basis for the inherency is that the method steps are the same for the claims and Fujita so that the same effect would result from the same compound that is administered and further that ischemia occurs in cases of hemorrhagic shock.

E) Applicant argues that Pinsky does not explicitly or inherently disclose treating hemorrhagic shock. But claim 1 administers CO in any amount to treat hemorrhagic shock. Pinsky administers the same CO. Thus, although, Pinsky did not use the phrase "hemorrhagic shock," but the examiner maintains that Pinsky anticipates claims 1-3, 10 and 11 because by applicant's own admission, ischemia occurs in hemorrhagic shock and treatment of ischemia by administration of CO treats ischemia, which occurs in hemorrhagic shock, therefore, Pinsky's administration of CO inherently treats hemorrhagic shock. Pinsky teaches that ischemia occurs in several cites (Examples 7 and 11). Applicant has also previously argued on the record that, Pinsky discloses that ""ischemic disorder" encompasses and is not limited to a peripheral vascular disorder, a venous thrombosis, a pulmonary embolus, a myocardial infarction, a transient ischemic attack, lung ischemia, unstable angina, a reversible ischemic neurological deficit, adjunct thromolytic activity, excessive clotting conditions, sickle cell anemia or a stroke disorder."

Applicant's attempt to invoke genus species relationship as it relates to ischemia and hemorrhagic shock is not persuasive to overcome the rejections because, since ischemia occurs in hemorrhagic shock, ischemia is a species and hemorrhagic shock is the genus so that the species, which in this case is ischemia, anticipates the genus of hemorrhagic shock.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 55 and 56 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fujita et al. ("Paradoxical rescue from ischemic lung injury by inhaled carbon monoxide driven by depression fibrinolysis," Nature Medicine, 7, 598-604, 2001) or Pinsky et al. (US 2005/0048133 A1) for reasons of record and reiterated herein below.

11. Fujita and Pinsky have been shown above individually to anticipate claim 1. None of these references cite the amount of CO administered to treat ischemia in ppm amounts as recited in claim 55. Regarding claim 56, it is within the capabilities of the artisan to determine how long the CO can be administered to effect the anticipated result of treating ischemia. The prior art teaches the general conditions of administering the CO to treat ischemia. And in general, when the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover optimum or workable ranges by routine experimentation. Therefore, taking the general teachings of the prior art, one having ordinary skill in the art at the time the invention was made would administer amount of CO for appropriate duration that would be effective in the treatment of ischemia and inherently hemorrhagic shock.

Response to Arguments

12. Applicant's arguments filed 1/12/09 have been fully considered but they are not persuasive.

13. Applicant argues that neither Fujita nor Pinsky teaches the method of claim 1. The examiner disagrees because both Pinsky and Fujita administer CO to a target, which is the method step of claim 1 and applicant had previously stated on the record that ischemia occurs in hemorrhagic shock. It is well known that ischemic conditions occur in hemorrhagic shock as evidenced at paragraph [0004] of Barshalom, IngentaConnect Detection of organ ischemia during hemorrhagic shock, and Pelc et al., in Radiology, 1998, pp 219-225. The artisan has the capability of administering an amount of CO in amounts that would be effective to treat ischemia

14. Claims 1, 2 and 57-65 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fujita et al. ("Paradoxical rescue from ischemic lung injury by inhaled carbon monoxide driven by depression fibrinolysis," Nature Medicine, 7, 598-604, 2001) or Pinsky et al. (US 2005/0048133 A1) in view of Peitzman et al. ("Hemorrhagic shock" in Curr Probl Surg. 1995 Nov. 32 (11): 925-1002 , abstract) for reasons of record and reiterated herein below.

15. Fujita and Pinsky have been shown above to individually anticipate claims 1 and 2. Fujita and Pinsky did not teach further transfusion of blood to treat the ischemic condition in

addition to the CO. However, Peitzman teaches that transfusion of blood is effective to treat hemorrhagic shock including ischemia. Claims 59-65 recites components that are part of the blood. Therefore, taking the teachings of the prior art, one having ordinary skill in the art at the time the invention was made, would have reasonable expectation of success that combining blood transfusion with CO administration would effectively treat ischemia and/or hemorrhagic shock because CO administration and blood transfusion has been shown in the art to treat ischemia/hemorrhagic shock.

Response to Arguments

16. Applicant's arguments filed 1/12/09 have been fully considered but they are not persuasive.

17. Applicant argues that neither Fujita nor Pinsky teaches the method of claim 1. The examiner disagrees because both Pinsky and Fujita administer CO to a target, which is the method step of claim 1 and applicant had previously stated on the record that ischemia occurs in hemorrhagic shock. It is well known that ischemic conditions occur in hemorrhagic shock as evidenced at paragraph [0004] of Barshalom, IngentaConnect Detection of organ ischemia during hemorrhagic shock, and Pelc et al., in Radiology, 1998, pp 219-225. Applicant argues that Peitzman fails to remedy the deficiencies of Fujita and Pinsky, which is treating hemorrhagic shock and therefore, neither Fujita nor Pinsky renders obvious the claims. The examiner disagrees. Peitzman is relied upon for teaching that transfusion of blood is effective to treat hemorrhagic shock including ischemia so that one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that combining blood transfusion with CO administration would effectively treat ischemia and/or hemorrhagic shock.

18. Declaration of Dr. Brian Zuckerbraun under 37 CFR 1.132:

19. The declaration under 37 CFR 1.132 filed 1/12/09 is insufficient to overcome the rejection of claims 1-3, 10 and 11 based upon rejections under 35 USC 102(b) by Fujita et al. ("Paradoxical rescue from ischemic lung injury by inhaled carbon monoxide driven by depression fibrinolysis," Nature Medicine, 7, 598-604, 2001) as set forth in the last Office action because: Declaration can not be used to overcome rejections under 35 USC 102.

20. The declaration under 37 CFR 1.132 filed 1/12/09 is insufficient to overcome the rejection of claims 1-3, 10 and 11 based upon rejections under 35 USC 102(e) by Pinsky et al. (US 2005/0048133 A1) as set forth in the last Office action because: Declaration can not be used to overcome rejections under 35 USC 102.

21. The declaration under 37 CFR 1.132 filed 1/12/09 is insufficient to overcome the rejection of claims 1, 2 and 55-65 based upon rejections under 35 USC 103 over Fujita et al. ("Paradoxical rescue from ischemic lung injury by inhaled carbon monoxide driven by depression fibrinolysis," Nature Medicine, 7, 598-604, 2001) and Pinsky et al. (US 2005/0048133 A1) as set forth in the last Office action because: While Dr. Zuckerbraun declares that ischemia and hemorrhagic shock are distinct medical conditions, Dr. Zuckerbraun has not provided an opinion that ischemia cannot occur in hemorrhagic shock and has not presented factual showing that ischemia cannot occur in hemorrhagic shock.

No claim is allowed.

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618